

EC DECLARATION OF CONFORMITY

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Ref. No: DC Instrument and Software/09

Phadia AB, Rapskatan 7P, P.O. Box 6460, 751 37 Uppsala, Sweden

hereby declare that the products listed below fulfil the requirements in the "Directive 98/79/EC of the European parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices" (IVDD), the Swedish Medical Devices Act (1993:584) and the regulation LVFS 2001:7. The products are classified as "General devices" (all devices other than those covered by IVDD Annex II and self-testing devices). Conformity assessment is performed according to IVDD Annex III.

Art. No.	Product Name
12-3500-01	Phadia 100
12-3800-01	Phadia 1000
12-3801-11	Phadia Information Data Manager Software Package
12-3900-01	Phadia 250
12-4000-00	Phadia 5000
12-4000-01	Phadia 5000E
12-4000-02	Phadia 5000E+E
12-4100-00	Phadia 2500
12-4100-01	Phadia 2500E
12-4100-02	Phadia 2500EE
12-4101-00	Phadia Prime

END OF LIST

2014-12-15

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Date



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Carina Magnusson, Regulatory Affairs Director